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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,122	CARNEY ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 45-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *62* is/are allowed.

6)☒ Claim(s) *1,4,45-61 and 63-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 23 February 2004 has been entered in full. Claims 2, 3 and 5-44 were cancelled. New claims 45-65 were added. Claims 1, 4, 45-65 are under examination.

Applicants' arguments and remarks filed 02 January 2004 have been entered.

The Declaration of Darrell H. Carney under 37 CFR 1.132 filed 05 January 2004 has been entered.

The application now complies with the requirements of 37 CFR 1.821-1.825.

Applicants have stated that a Supplemental Information Disclosure Statement (IDS) was filed on 25 July 2003. Applicants have requested entry and consideration of the IDS. The information disclosure statement, filed 25 July 2003, was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 2, 3, 5, 11-16 and 35-43 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 4-7 of the previous Office Action (30 June 2003) is *withdrawn* in view of the amendment (23 February 2003).

The rejection of claims 2, 3, 5, 11-16 and 35-43 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 7-8 of the previous Office Action (30 June 2003) is *withdrawn* in view of the amendment (23 February 2003).

The rejection of claims 5, 11, 12 and 35-43 under 35 U.S.C. 112, second paragraph as set forth at pages 8-9 of the previous Office Action (30 June 2003) is *withdrawn* in view of the amendment (23 February 2003).

The rejection of claims 2-5, 11,12, 16 and 35-37 under 35 U.S.C. 102(b) as being anticipated by Simmons *et al.*, "Acceleration of Rat Femoral Fracture Healing by a Synthetic Thrombin Peptide, meeting held 20 November 1998 (IDS#AS3 submitted by Applicant), as set forth at page 9 of the previous Office Action (30 June 2003) is *withdrawn* in view of the amendment (23 February 2003).

The rejection of claims 13-15 under 35 U.S.C. 103(a) as being unpatentable over Simmons *et al.* (IDS#AS3 submitted by Applicant) in view of Schmitz, US Patent No. 4,637,931, as set forth at pages 9-11 of the previous Office Action (30 June 2003) is *withdrawn* in view of the amendment (23 February 2003).

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 1, 4, 45-60 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of stimulating bone growth at a site in a subject in need of osteoinduction (or bone graft), said method comprising the step of administering to the site a therapeutically effective amount of an agonist of the non-proteolytically activated

thrombin receptor wherein the agonist is a thrombin derivative comprising a polypeptide 23 amino acids in length and is represented by the following structure

Arg-Gly-Asp-Ala-**R** wherein **R** is a serine esterase conserved sequence and wherein Asp-Ala of said structure comprise the first two amino acids of the serine esterase conserved sequence **OR**

an agonist comprising SEQ ID NO:5 **OR**

an agonist comprising SEQ ID NO:6,

does not reasonably provide enablement for:

a method of stimulating bone growth at a site in a subject in need of osteoinduction (or bone graft), said method comprising the step of administering to the site a therapeutically effective amount of an agonist of the non-proteolytically activated thrombin receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 4-7 of the previous Office Action (30 June 2003).

Applicants' arguments have been fully considered and are deemed partly persuasive. Applicants cite pages in the specification for support regarding the activity of NPAR agonists and methods for identifying, screening and making NPAR agonists. Applicants also cite US Patent Nos. 5,352,664 and 5,500,412 for support. Applicants state that specific examples of NPAR agonists provided in the specification include thrombin peptide derivatives comprising a polypeptide represented by the structural formula Asp-Ala-R, wherein R is a serine esterase conserved sequence, such as the

thrombin peptide derivative of SEQ ID NO:5 and SEQ ID NO:6. Applicants state that since thrombin peptide derivative TP508 has been shown to be osteoinductive, one skilled in the art would reasonable expect that other NPAR agonist can be successfully employed to stimulate bone formation at a site where bone formation would not occur if the site was left untreated. Applicants state that the Carney Declaration provides evidence that one skilled in the art would expect that other NPAR agonists can be successfully employed to stimulate bone formation at a site where bone formation would not occur if the site was left untreated. Applicants state that the USPTO relied primarily on data for TP508 in issuing the '664 and '412 with claims reciting a broader range of NPAR agonists. Therefore claims at least as broad with respect to TP508 analogs in the '664 and '412 patents should be allowable in the present application.

The Carney Declaration under 37 CFR 1.132 filed 05 January 2004 is partly sufficient to overcome the 112, first paragraph, scope of enablement rejection. The Examiner will use the specification of US Patent No. 5,352,664 which is incorporated by reference in the instant application. US Patent No. 5,352,664 states that *in addition* to the thrombin receptor-binding domain, the stimulatory (agonistic) polypeptides possess a sequence of amino acids having sequences derived from the N-terminal amino acids of a decapeptide previously shown to be highly conserved among serine proteases (column 3, lines 42-48). The thrombin receptor-binding domain is taught as Arg-Gly-Asp-Ala (column 4, lines 22-26). The serine esterase conserved sequence is also taught (column 7, lines 3-10). Thus, the background of the instant patent does not teach agonist (stimulatory peptides) of non-proteolytically activated thrombin receptor

modified to an unlimited extent relative to those exemplified as is claimed. The instant claims encompass any type of agonist of the non-proteolytically activated thrombin receptor, functional equivalent, fragments or substitutions thereof. Furthermore, Example 4 of US Patent No. 5,352,664 teaches that peptide 508-530 (23 amino acid sequence comprising AGYKPDEGKRGDACEGDSGGPFV) generated mitogenic signals through its interaction with the thrombin receptor. *However*, peptide 519-530 (12 amino acid sequence comprising DACEGDSGGPFV) and peptide 517-520 (4 amino acid sequence comprising RGDA) did not exhibit mitogenic activity as great as peptide 508-530 (Figure 6) and took a much greater concentration to compete with alpha-thrombin binding (Table 1). Thus to summarize, US Patent No. 5,352,664 teaches a specific domain (thrombin receptor binding domain), conserved sequences (serine esterase conserved sequence) and a minimum amino acid length (23 amino acids) of stimulatory agonist of the non-proteolytically activated receptor. Lastly, the allowed claims of both US Patent No. 5,352,664 and US Patent No. 5,500,412 recite specific claim language regarding sequence and amino acid length of stimulatory thrombin derivatives. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

Claims 1, 4, 45-60 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pages 7-8 of the previous Office Action (30 June 2003).

The specification provides adequate written description for SEQ ID NO:5, SEQ ID NO:6 and a thrombin derivative comprising a polypeptide 23 amino acids in length and is represented by the following structure Arg-Gly-Asp-Ala-**R** wherein **R** is a serine esterase conserved sequence and wherein Asp-Ala of said structure comprise the first two amino acids of the serine esterase conserved sequence, but fails to provide written description for any thrombin peptide derivative, truncated fragments or physiologically functional equivalent thereof.

Applicants state that detailed characteristics for the NPAR agonists are recited in the rejected claims. Applicants state that the specification teaches that NPAR agonists are compounds which stimulate or activate NPAR and that methods for assaying for NPAR activation are disclosed in the specification and the recited patents. Applicants conclude by stating that the knowledge and level of skill in the field is high and a person skilled in the art would recognize from the disclosed characteristic that Applicants were in possession of the claimed genus of NPAR agonists at the time the present application was filed.

Applicant's arguments have been fully considered but are not deemed persuasive because *methods for identifying and screening for NPAR agonists do not correlate to disclosure of NPAR agonists*. The genus of "agonist of the non-proteolytically activated receptor " is being claimed by function alone. There is no structural element correlative with the function, nor is there any indication that Applicant

is in possession of any agonist of the non-proteolytically activated receptor. Furthermore, the instant species of agonist are not representative of the broad genus being claimed because the recitation of "an agonist of the non-proteolytically activated receptor", broadly encompasses lipids, protein, chemical analogs, polynucleotides, etc. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Thus, there is insufficient descriptive support for the instant genus. The instant method requires the use of undisclosed agonist or functional analogs. The specification does not demonstrate possession of the instant process steps which require the use of undisclosed compounds. The specification provides insufficient written description to support the genus encompassed by the claim. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 102(b)

Claims 1, 4, 45-53, 56 and 60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Simmons *et al.,* "Acceleration of Rat Femoral Fracture Healing by a Synthetic Thrombin Peptide", meeting held 20 November 1998 (IDS#AS3 submitted by Applicant, Paper No. 8). The basis for this rejection is set forth at page 9 of the previous Office Action (30 June 2003).

Applicants state that claims relate to the use of NPAR agonists, including TP508 (SEQ ID NO:5), in stimulating bone growth at a site in need of osteoinduction or in need of a bone graft. Applicants state that osteoinduction is defined in the subject application at page 3, lines 20-21 as a site at which bone growth would not occur if the site were left

untreated. Such sites in need of osteoinduction include segmental bone gaps, bone voids and at non-union fractures. The healing process (bone regeneration) at such a site does not occur without osteoinduction or bone grafting.

Applicants state that Example 2 of the specification teaches that an injury resulting in a segmented gap did not heal when it was left untreated; bone regeneration (osteoinduction) did not occur at the segmented gap. When the site was treated with TP508, osteoinduction was induced where it did not occur without TP508. Applicants argue that Simmons *et al.* teach that TP508 enhanced the mechanical strength and accelerated the progression of rat femoral fracture healing. Applicants maintain that healing of this fracture (bone regeneration) was occurring prior to TP508 treatment, indicating that treatment (including bone grafting and osteoinduction) was not required for normal bone growth. Simmons *et al.* teach that TP508 enhanced the mechanical strength and accelerated the rate of normal fracture healing in a fracture that normally heals without treatment. Applicants maintain that Simmons *et al.* do not teach or suggest the use of TP508 for stimulating bone formation at a site in need of osteoinduction or bone grafting, i.e. at a site where bone growth would not occur if the site was left untreated. Applicants assert that claims are not anticipated by the Simmons *et al.* reference.

Applicants' arguments have been fully considered but are not deemed persuasive because the term "osteoinduction" as defined by the instant specification is not the accepted art definition of osteoinduction. The Examiner has provided a reference to support the argument. Albrektsson *et al.* (Abstract, European Spine

Journal 2001) define osteoinduction as the process by which osteogenesis is induced. It is a phenomenon regularly seen *in any type of bone healing process*. Albrektsson *et al.* state that in a bone healing situation, such as a fracture, the majority of bone healing is dependent on osteoinduction. Applicant cannot define a term of art that is repugnant to its accepted meaning in the art. Please MPEP 608.01(o). Simmons *et al.* teach methods of administering TP508 to stimulate bone growth at a site in rats in need of bone repair due to fracture. Furthermore, a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Simmons *et al.* and the instant specification both teach the administration of TP508 (SEQ ID NO:5).

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 103(a)

Claims 4, 57-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Simmons *et al.*, "Acceleration of Rat Femoral Fracture Healing by a Synthetic Thrombin Peptide", meeting held 20 November 1998 (IDS#AS3 submitted by Applicant, Paper No. 8) in view of in view of Schmitz, US Patent No. 4,637,931. The basis for this rejection is set forth at pages 9-11 of the previous Office Action (30 June 2003).

Applicants state that Schmitz does not teach or suggest the use of pharmaceutical compositions comprising an NPAR agonist, such as TP508 (SEQ ID NO:5) in stimulating bone growth at a site in need of osteoinduction and thus the reference does not cure the deficiencies of the Simmons *et al.* reference. Applicants

state that the Examiner has not identified a suggestion in the prior art of the desirability of the proposed combination of references.

Applicants' arguments have been fully considered but are not deemed persuasive. The MPEP 2143 states (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Contrary to Applicants' assertion, the Examiner used the teachings of the prior art and the knowledge available to one of ordinary skill in the art, not the instant specification, to piece together the combination of references to establish a prima facie case of obviousness. Furthermore, the Examiner discussed the motivation and reasonable expectation of success using the prior, not Applicants' disclosure. The Examiner has already discussed the reasons why claims 4, 57-59 are anticipated by the Simmons *et al.* (reference teaches pharmaceutical compositions comprising TP508 {SEQ ID NO:5}). As was stated in the last Office Action, Simmons *et al.* do not teach an

implantable osteoconductive matrix comprising polylactic acid/polyglycolic acid homopolymer (PLA/PGA) or copolymer. As was stated in the last Office Action, Schmitz teaches methods comprising implanting at the site of the broken osseous tissue a therapeutically effective amount of a composition comprising decalcified freeze dried bone incorporated into a biodegradable polymeric matrix of PLA/PGA. Schmitz teaches that PGA and PLA have demonstrated an accelerate rate of osseous wound healing and produce only a slight inflammatory response. Schmitz teaches that PLA and PGA eliminates the need for a second surgical procedure in the host, biodegrades without forming toxic metabolites, has the ability to act as a trestle for bony ingrowths and may also possess osteogenic potential. Schmitz provides motivation. Based on the Schmitz discussion, it would be obvious to one skilled in the art to combine the teachings of Simmons *et al.* and Schmitz to make the instant invention.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

New claims 63 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 63 is drawn to a method of stimulating bone growth in a subject at an ectopic site, said method comprising the step of administering to the ectopic site a therapeutically effective amount of a C-terminal amidated peptide of 23 amino acids comprising the sequence of Ala-Gly-Try-Lys-Pro-Asp-Glu-Gly-Lys-Arg-Gly-Asp-Ala-Cys-Glu-Gly-Asp-Ser-Gly-Gly-Pro-Phe-Val (SEQ ID NO:6).

Claim 64 is drawn to a method of stimulating bone growth in a subject at a site requiring dental or periodental reconstruction, said method comprising the step of administering to the site a therapeutically effective amount of a C-terminal amidated peptide of 23 amino acids comprising the sequence of Ala-Gly-Try-Lys-Pro-Asp-Glu-Gly-Lys-Arg-Gly-Asp-Ala-Cys-Glu-Gly-Asp-Ser-Gly-Gly-Pro-Phe-Val (SEQ ID NO: 6).

The instant claims are not supported by an enabling disclosure for the following reasons. The instant specification defines ectopic sites as where bone would not normally be found such as a site in need of a bone graft or bone fusion (page 4, lines 4-6). Claim 63 as recited encompasses "any site" where bone would not normally be found. Any site can include the heart, liver, lung, etc. The specification fails to teach a method of stimulating bone growth in a subject at "any site" comprising administering at "any site" a C-terminal amidated peptide of 23 amino acids comprising the sequence of SEQ ID NO:6. procedure. The specification fails to teach why such a treatment is desirable and what subjects are in need of such treatment.

Lastly, the specification fails to teach that a C-terminal amidated peptide of 23 amino acids comprising the sequence of SEQ ID NO:6 can stimulate bone growth in a subject at a site requiring dental or periodental reconstruction. Sigurdsson *et al.*

(reference cited in the instant specification, J. Periodontol., 1995) teach the periodontal regenerative potential of various proteins (page 512, 1st paragraph). Sigurdsson *et al.* employ the critical size supraalveolar periodontal defect model in the beagle dog. Sigurdsson *et al.* teach that the defect model allows for discriminating quantitative evaluation of periodontal healing. Sigurdsson *et al.* state that the results obtained in this particular model are amenable to a straightforward interpretation regarding the spatial origin of the healing tissues (page 512, 3rd parargraph-4th paragraph). Siggurdson *et al.* teach periodontal and cementum regeneration with space providing expanded polytetrafluoroethylene (ePTFE) membrane and recombinant human bone morphogenetic-2 (rhBMP-2) protein (page 517). Sigurdsson *et al.* teach that at least two distinct mechanisms may be postulated to reestablish the original tissue relationship in the periodontium. One involves migration and proliferation of already differentiated cells into the wound site from existing tissue resources. The other mechanism entails grouping of mesenchymal stem cells (page 519). Siggurdson *et al.* state that prior to clinical studies with these material, it is necessary to investigate the healing of experimental periodontal defects where wound closure leaves the teeth in a transgingival position or exposed to periodontal disease. Long term studies are also needed to assess probable remodeling of regenerated tissues and to establish the structural and functional stability of these tissues over time (page 520).

The instant specification fails to disclose that SEQ ID NO:6 has those properties needed for periodental regeneration. The specification does not teach that SEQ ID

NO:6 can induce migration and proliferation of differentiated cells into wounds or posses other properties postulated by Siggurdson *et al.* Siggurdson *et al.* state that while BMP-2 has been demonstrated to induce the complete sequence of endochondral ossification, this pathway does not explain the observed regeneration of the other periodontal structures (page 519, 2nd paragraph). The osteogenic potential of SEQ ID NO:6 would not translate to potential uses in periodontal reconstructive therapy, until the protein is evaluated using a recognized model. The prior art does not suggest that proteins with osteogenic properties also possess periodental regeneration activities. The specification fails to teach the use of art recognized animal models and working examples (surgical controls, radiographic and histologic assays) to demonstrate periodental growth activity of SEQ ID NO:6. The animal model employed in the instant specification would not correlate to methods of periodontal regeneration.

Due to the large quantity of experimentation necessary to show a correlation between a C-terminal amidated peptide of 23 amino acids comprising the sequence of SEQ ID NO:6 and dental/periodontal reconstruction, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding sites wherein said peptide can stimulate bone growth, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, Second Paragraph

New claims 61 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 61 and 65 appear to be drawn to the same method. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper form.

Allowable Subject Matter

Claim 62 is allowable.

Conclusion

Claims 1, 4, 45-61, 63-65 are rejected.

Claim 62 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/11/04

Elizabeth C. Kemmerer
ELIZABETH KEMMERER
PRIMARY EXAMINER